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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,949	04/19/2001	Jean-Louis Excoffier	01-02 US	4507

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EXAMINER

MAHATAN, CHANNING

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

Office Action Summary

Application No.

09/839,949

Applicant(s)

EXCOFFIER, JEAN-LOUIS

Examiner

Channing S Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-8,10-43 and 57-81 is/are pending in the application.
- 4a) Of the above claim(s) 30-42 and 57-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-8,10-29,43-45 and 67-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-43 and 57-81 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

REQUEST FOR CONTINUED EXAMINATION

Since this application is eligible for the transitional procedure of 37 C.F.R. § 1.129(a), and the fee set forth in 37 C.F.R. § 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 C.F.R. § 1.129(a). Applicants' submission after final filed on 22 September 2003 has been entered.

APPLICANTS' ARGUMENTS

Applicants' arguments filed 22 September 2003 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIMS NOT PREVIOUSLY PRESENTED

Newly submitted claims 57-66 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The claims are directed to a "computer implemented method for determining chromatogram consistency" whereas the elected invention is directed to a "computer implemented method for classifying chromatograms". Classification and determination of consistency have different intend goals and steps/functions for said methods. Thus, the methods are directed to independent and/or distinct inventions since it is indicated one method is to determine consistency while the other is to classify (elected invention). Further, the final step of

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claim 57 (lines 10-11) is to “determine whether each chromatogram datum of the data set is consistent or inconsistent with the reference based on the comparison”.

Since Applicants have received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 57-66 are withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-3, 5-8, 10-29, 43-45, and 67-81. Claims 30-42 and 57-66 are withdrawn from examination as directed to a non-elected invention.

Claims Rejected Under 35 U.S.C. § 101

35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

NON-STATUTORY SUBJECT MATTER

Claims 1-3, 5-8, 10-18, 44, and 45 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter as necessitated by amendment. The claimed invention is directed to a “method for classifying chromatograms”.

M.P.E.P. section entitled “Nonstatutory Subject Matter” (pages 2100-12, Columns 1-2) states:

Claims to processes that do nothing more than solve mathematical problems or manipulate abstract ideas or concepts are more complex to analyze and are addressed below. If the “acts” of a claimed process manipulate only numbers, abstract concepts or ideas, or signals representing any of the foregoing, the acts are not being applied to appropriate subject matter. Schrader, 22 F.3d at 294-95, 30 U.S.P.Q.2d at 1458-59. Thus, a process consisting solely of mathematical operations, i.e., converting one set of numbers into another set of numbers, does not manipulate appropriate subject matter and thus cannot constitute a statutory process.

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Further, M.P.E.P. section entitled “Statutory Process Claims” (page 2100-15, Column 1-2) states:

A claim that requires one or more acts to be performed defines a process. However, not all processes are statutory under 35 U.S.C. 101. *Schrader*, 22 F.3d at 296, 30 U.S.P.Q.2d at 1460. To be statutory, a claimed computer-related process must either: (A) result in a physical transformation outside the computer for which a practical application in the technological arts is either disclosed in the specification or would have been known to a skilled artisan (discussed in i) below), or (B) be limited to a practical application within the technological arts (discussed in ii) below). See *Diamond v. Diehr*, 450 U.S. at 183-84, 209 U.S.P.Q. at 6 (quoting *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1877)) (“A [statutory] process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.... The process requires that certain things should be done with certain substances, and in a certain order; but the tools to be used in doing this may be of secondary consequence.”). See also *Alappat*, 33 F.3d at 1543, 31 U.S.P.Q.2d at 1556-57 (quoting *Diamond v. Diehr*, 450 U.S. at 192, 209 U.S.P.Q. at 10). See also *id.* at 1569, 31 U.S.P.Q.2d at 1578-79 (Newman, J., concurring) (“unpatentability of the principle does not defeat patentability of its practical applications”) (citing *O'Reilly v. Morse*, 56 U.S. (15 How.) at 114-19). If a physical transformation occurs outside the computer, a disclosure that permits a skilled artisan to practice the claimed invention, i.e., to put it to a practical use, is sufficient. On the other hand, it is necessary for the claimed invention taken as a whole to produce a practical application if there is only a transformation of signals or data inside a computer or if a process merely manipulates concepts or converts one set of numbers into another.

The computation steps/processes of claims 1-3, 5-8, 10-18, 44, and 45 are merely “mental” processes of performing mathematical operations (manipulation of numbers) applied to a computer. Absent from the instant claims is a classification scheme/categories for the classifying step (claim 1, line 20). Further, instant claim 1 (line 19) recites the step of “comparing the first and second data set to produce a comparison result, however, does not indicate what the comparison result represents. It is acknowledged claims 15, 16, and 17 recite the limitations “the act of comparing comprises determining a degree of similarity between the first and second data set”/ “the act of comparing comprises determining a degree of dissimilarity between the first and second data set”/“the act of comparing comprises-determining-distance-between-vectors associated with the first and second data set”, respectively. While these limitations recite particular acts of comparison the independent claim 1 fails to indicate a classification scheme/categories for these comparison results (i.e. similar, dissimilar, distance vector). In the

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absence of a classification scheme/categories and what the comparison result (i.e. claim 1) is for the act of “classifying the first and second chromatograms based on the comparison result” yields no concrete, tangible, or useful result by the claimed method. The claimed computer-implemented method recites steps, which manipulates chromatogram data (i.e. receiving, adjusting, reducing, etc.), but does not classify into particular or specific classes that one of ordinary skill in the art would find to be tangible, concrete, and useful information and therefore the claims fail to recite statutory subject matter.

Applicants’ state in the amendment filed 22 September 2003:

“Claim 1 has been amended to recite “classifying the first and second chromatograms based on the comparison result.” Therefore, applicant submits that claim 1 as amended satisfies the requirements of 35 U.S.C. 101.”

The amendment to claim 1 does not satisfy the requirements of 35 U.S.C. 101 and is addressed above.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

NEW MATTER

Claim 19 and all claims dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The introduction of “a classification module to classify the chromatogram corresponding to the reduced data set” in claim 19 (line 10) in the amendment filed 22 September 2003 is considered new matter. It is acknowledged the specification indicates several distinguishing modules (i.e. data adjustment module (page 14, lines 11-13), reduction module (page 14, lines 13-15), and comparison module (page 14, line 15)), however, fails to specifically provide a “classification module to classify the chromatogram corresponding to the reduced data set” or a “classification module. The original disclosure was searched for the phrase “classification module”, however, none was found and none is apparent. Additionally, Applicants failed to provide support for the above amendment to claim 19. Therefore, the introduction of “a classification module to classify the chromatogram corresponding to the reduced data set” in claim 19 is considered NEW MATTER.

SCOPE OF ENABLEMENT

Claims 1-3, 5-8, 10-29, 43-45, and 67-81 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method, system, and computer useable medium for classifying chromatograms into similar, dissimilar, and distance-vector categories, does not reasonably provide enablement for all classification schemes/categories as encompassed by then instant claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q. 2d 1400 at 1404 (C.A.F.C. 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3)

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the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Again, the specification states "...the invention provides a method for reducing each chromatogram to a data set that can be compared to another such data set, producing a comparison result that indicates the similarity or dissimilarity of the two chromatograms" (page 3, lines 6-8), wherein specific similarity and dissimilarity equations are disclosed on pages 11 of the specification. The office action mailed 31 December 2002 stated the following commensurate scope taught within the specification but absent from the instant claims:

"Applicant's enablement is limited to "adjusting data in the first and second regions of interest comprising centering an analysis window around one or more trace features in a given region of interest" (instant claim 4); "reducing the first and second chromatogram data to the first and second data sets: comprising determining an integral of the first and second chromatogram data and plotting against a time axis; determining a set of time points; and forming arrays of data set values based upon the set of time points and corresponding integral values for the set of time points" (instant claim 9); "Similarity Equation"(Eq. 5); "Dissimilarity Equation" (Eq. 6); and "Distance Equation" (Eq. 7) as indicated on pages 11-12 of the specification.

The classifying step of the instantly claimed invention embraces broad classification schemes beyond that taught and/or described by the specification. For example, chromatographic data could be classified into: 1) sets of attributes (i.e. name, data type, etc.); 2) erroneous/accurate

basecall; or 3) to particular functions (i.e. enzyme, antibody, etc). The specification only discloses the classification of chromatograms into similar, dissimilar, and/or distance categories (i.e. Equations 5, 6, and 7). The specification is devoid of procedures for the identification/comparison of, for example, attributes, basecall, and function and for the

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classification of chromatographic data based upon these identification/comparison results.

Thus, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicants' arguments in the amendment filed 22 September 2003 is directed to computer programming (i.e. creation of software). It is acknowledged the act of computer programming is within the ability of one of skill in the art to produce. However, the claims (as written) broadly encompass any form of classifying. Absent are the functions for the classification of chromatogram data by which one of skill in the art can create programming code. Therefore, without the knowledge of any classification classes and comparisons/decisions one would be unable to create a program commensurate in scope with the claimed method as written.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 70 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claims 6 (line 1), 70 (line 2), and all claims dependent therefrom have been amended to recite the phrase "flawed data" which is vague and indefinite. It is acknowledged that the specification (page 6, lines 16-30) describes "bad" as flawed data ("a peak that exceeds a threshold characteristic") and that a "bad data filter could be employed to determine if a

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particular chromatographic trace corresponds to flawed data". However, the disclosure fails to provide further meaning or limitation to the term "threshold characteristic"; absent is "the point or value above which something true or will take place and below which is not or will (take place)" which Applicants' regard as "flawed data". Thus, given the broad concepts provided for by the disclosure, it is unclear what applicant refers to as "flawed data". Clarification of the metes and bounds of this limitation, via clearer claim language, is required.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380 (until 12 January 2004) and (571) 272-0717 (after 12 January 2004). The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

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Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date:

December 24, 2003

Examiner Initials:

GSM

Marianne P. Allen

**MARIANNE P. ALLEN
PRIMARY EXAMINER**

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